Maintaining the risk : benefit relationship

FDA's role in medical product risk management
— presently tries to develop a toolbox

Sources of risks!

(Avoidable and Unavoidable side effects

RCT 1962 amendment of FD & C act

Labelling is part of risk management

Products to be outmoded

Surveillance as a part of risk management

Tools; 2) Change behaviors
1) Educate users
3) Reduce errors
4)

Use of SAB is a tool

Information of public - alerts is a tool

Rarely used

Registries of users

restricted - controlled distribution

spontaneous AE reporting

Communication with consumers

How many retailers, subjects will cooperate?

Following tests

Hyperpolarised gas lung investigation for ACCORD surveillance?

⇒ Case control study

Source: https://www.industrydocuments.ucsf.edu/docs/mgpj0001